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Morris

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(54) **METHOD FOR MONITORING BOLUS DELIVERY**

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(52) **U.S. Cl.** **604/508**

(58) **Field of Classification Search** .... 604/65–67, 604/500, 507, 508, 509, 510, 511, 512, 513; 128/DIG. 12, DIG. 13
See application file for complete search history.

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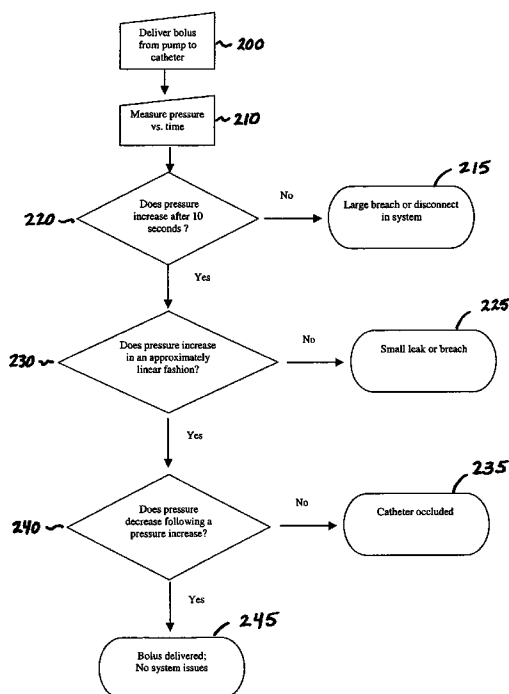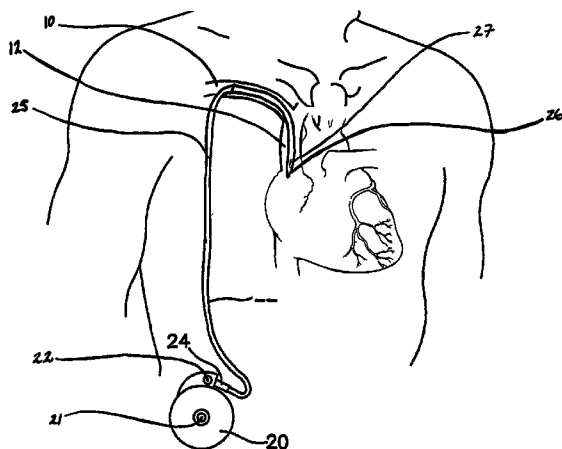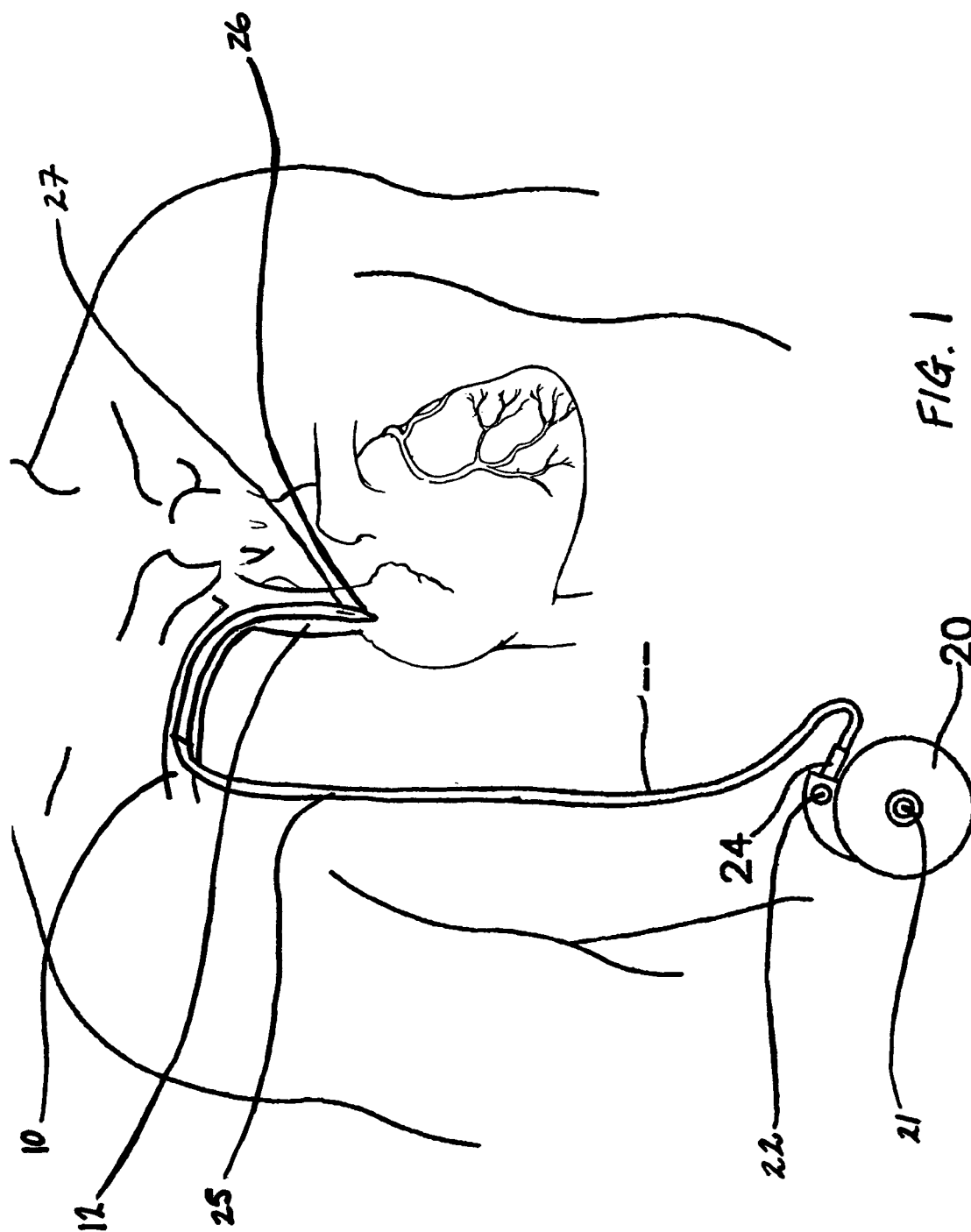| 4,898,576 A | * | 2/1990 | Philip .... 604/505 |
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(57) **ABSTRACT**

A method for monitoring a bolus delivered to a pressure-responsive valve of a fluid infusion catheter includes delivering the bolus through the infusion catheter over a period of time lasting between approximately one minute and approximately 60 minutes and observing a measured pressure versus time during the bolus delivery.
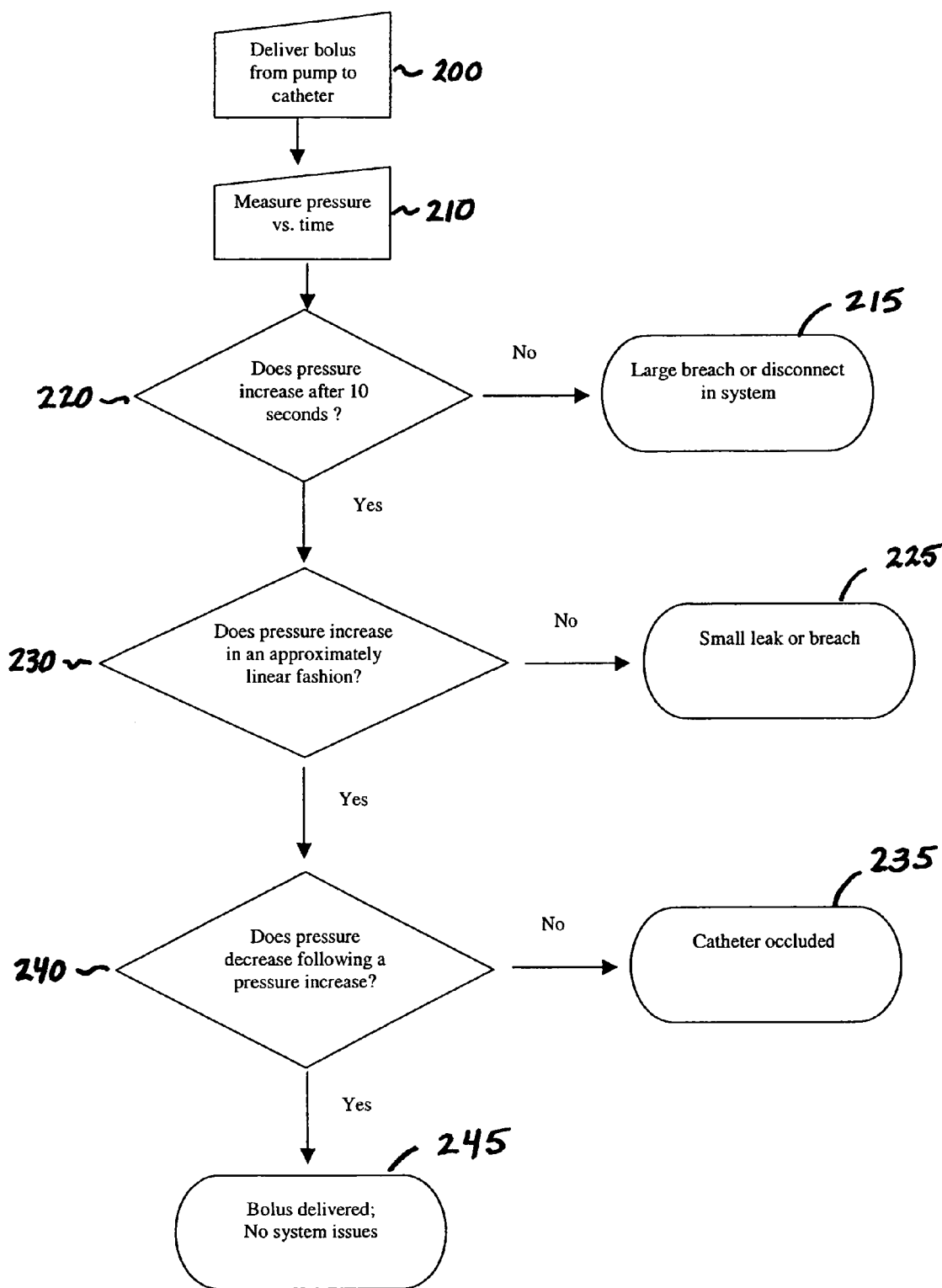
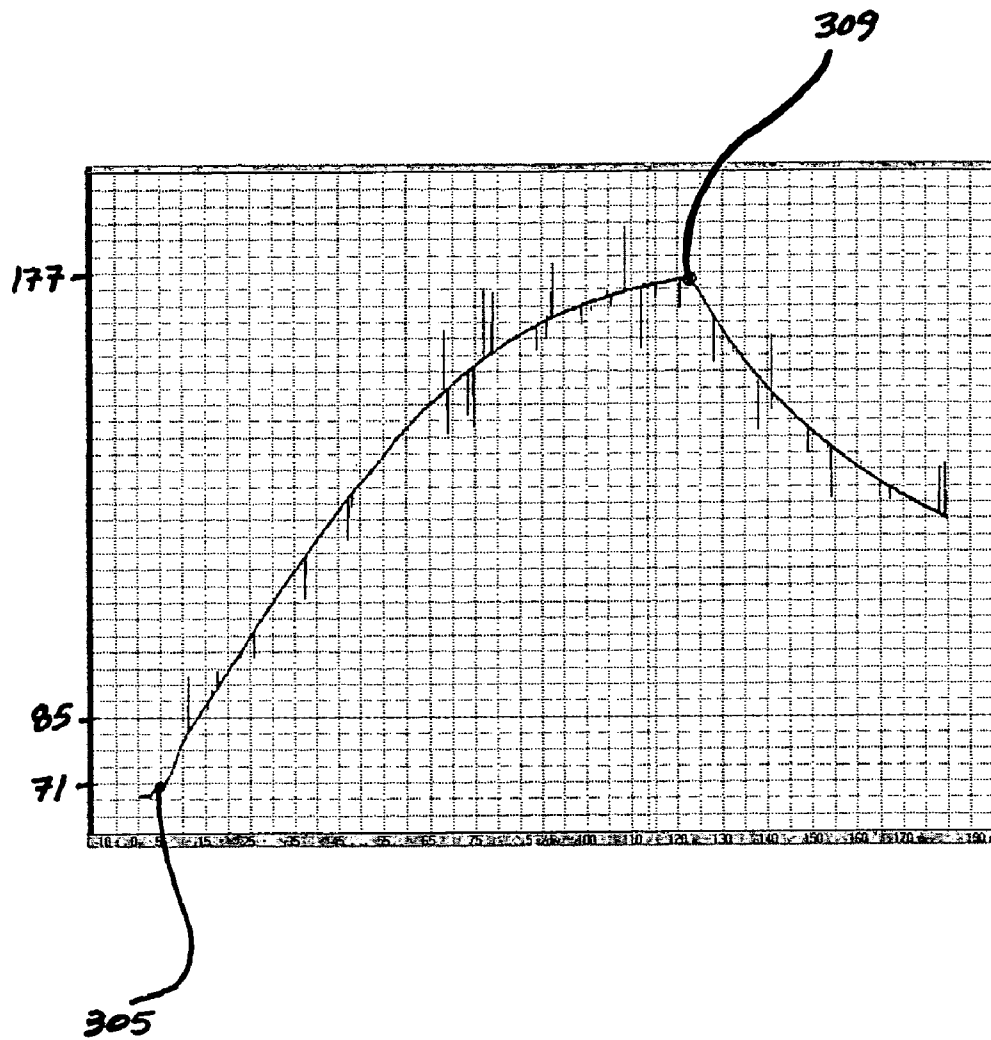**14 Claims, 5 Drawing Sheets**

FIG. 1

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┌─────────────────┐
│  Deliver bolus  │
│  from pump to   │ ～ 200
│    catheter     │
└────────┬────────┘
         │
         ▼
┌─────────────────┐
│ Measure pressure│ ～ 210
│    vs. time     │
└────────┬────────┘
         │
         ▼
      ◇ 220 ～
   Does pressure              No      ┌──────────────────────┐  ～ 215
   increase after 10   ──────────────►│ Large breach or disconnect │
   seconds ?                          │      in system        │
      ◇                               └──────────────────────┘
      │ Yes
      ▼
   ◇ 230 ～
   Does pressure increase      No     ┌──────────────────────┐  ～ 225
   in an approximately  ─────────────►│  Small leak or breach │
   linear fashion?                    └──────────────────────┘
   ◇
   │ Yes
   ▼
   ◇ 240 ～
   Does pressure                No    ┌──────────────────────┐  ～ 235
   decrease following a ─────────────►│   Catheter occluded   │
   pressure increase?                 └──────────────────────┘
   ◇
   │ Yes
   ▼
┌──────────────────────┐  ～ 245
│   Bolus delivered;    │
│   No system issues    │
└──────────────────────┘
```

FIG. 2

FIG. 3A
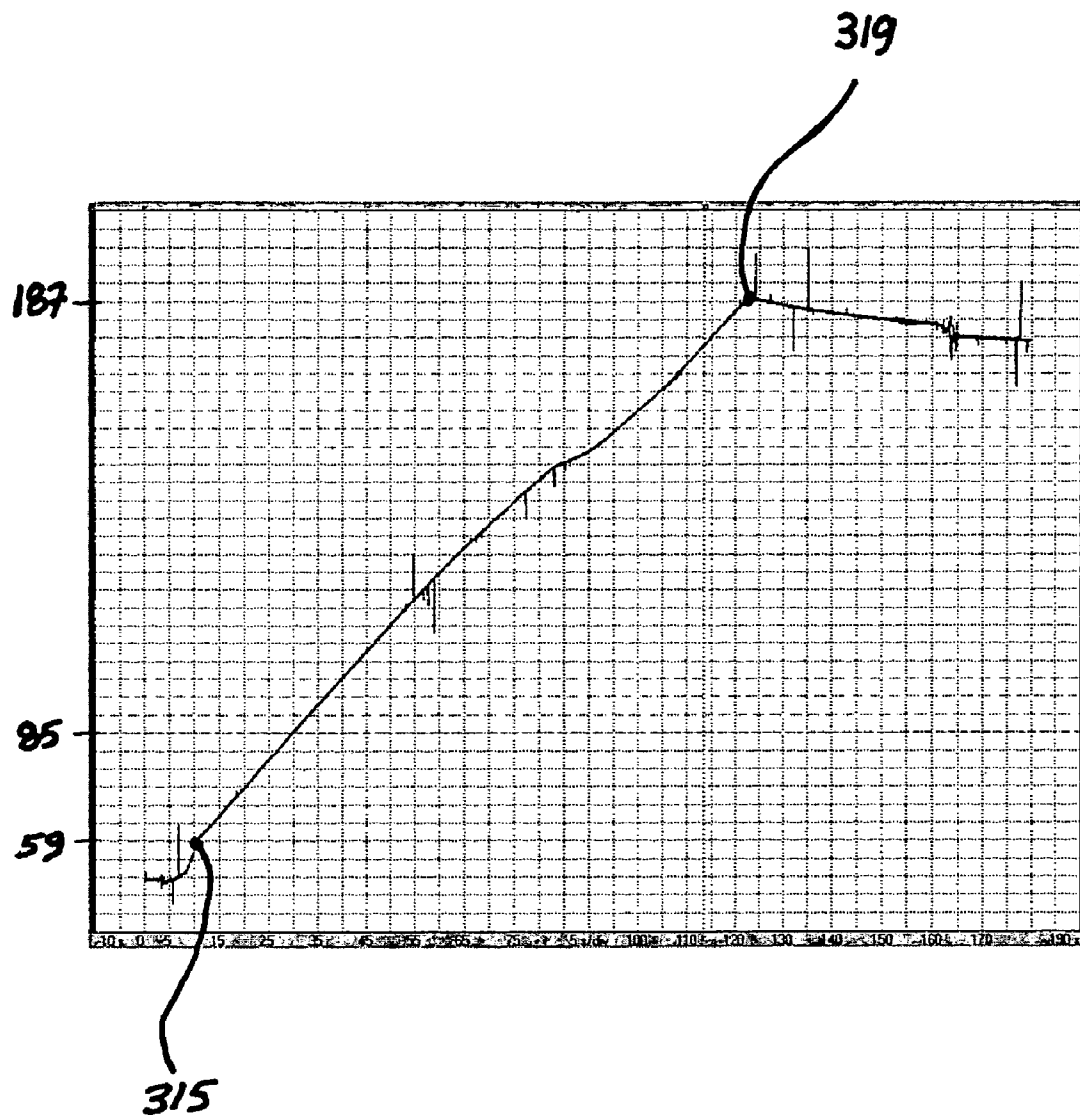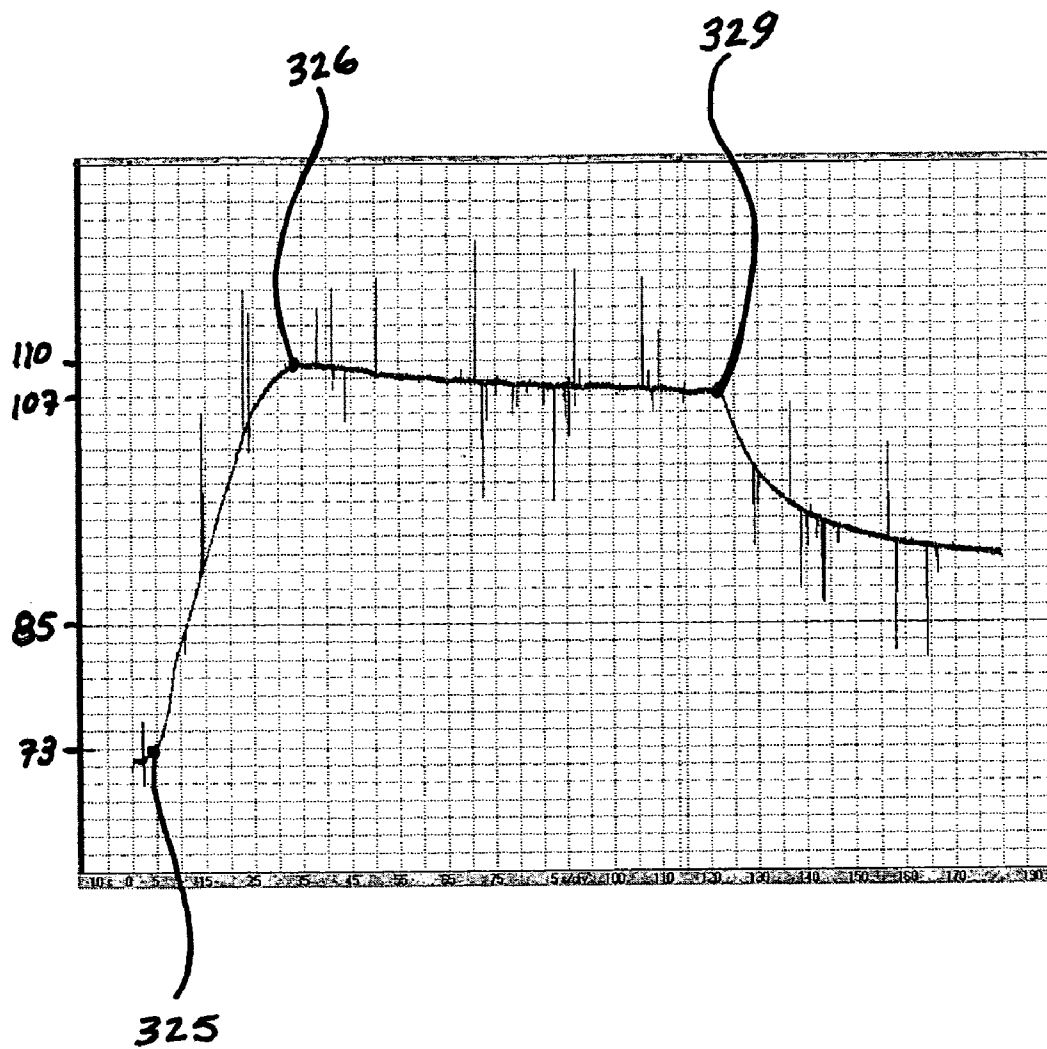
FIG. 3B

FIG. 3C

METHOD FOR MONITORING BOLUS DELIVERY

TECHNICAL FIELD

The present invention relates to the field of implantable drug infusion devices and more particularly to a method for monitoring boluses delivered by an implantable drug infusion device through an infusion catheter.

BACKGROUND

Implantable drug infusion devices are used to provide patients with programmable long-term dosage or infusion of a drug or any other therapeutic agent. These devices typically include a pump and a catheter attached to the pump and extending to a target site through which boluses of infusate are delivered. It is desirable to monitor such devices to verify bolus delivery or to identify causes of unsuccessful bolus delivery, such as leakage or occlusion.

BRIEF DESCRIPTION OF THE DRAWINGS

The following drawings are illustrative of particular embodiments of the invention and therefore do not limit its scope, but are presented to assist in providing a proper understanding of the invention. The drawings are not to scale (unless so stated) and are intended for use in conjunction with the explanations in the following detailed description. The present invention will hereinafter be described in conjunction with the appended drawings, wherein like numerals denote like elements, and:

FIG. **1** is a schematic diagram of an implanted drug infusion device wherein embodiments of the present invention may be practiced;

FIG. **2** is a flowchart detailing a method according to one embodiment of the present invention;

FIG. **3**A is a plot of pressure versus time measured during a bolus delivery in leaky device;

FIG. **3**B is a plot of pressure versus time measured during a bolus delivery in an occluded device; and

FIG. **3**C is a plot of pressure versus time measured during a successful bolus injection.

DETAILED DESCRIPTION OF THE DRAWINGS

The following detailed description is exemplary in nature and is not intended to limit the scope, applicability, or configuration of the invention in any way. Rather, the following description provides a practical illustration for implementing exemplary embodiments of the invention.

FIG. **1** is a schematic diagram of an implanted drug infusion device wherein embodiments of the present invention may be practiced. FIG. **1** illustrates the device including a pump **20**, implanted in an abdominal region of a patient, and an infusion catheter **25**, coupled to pump **20** via a connector **24**, extending into a superior vena cava **12** via a subclavian vein **10**. FIG. **1** further illustrates catheter **25** including a valve **27** positioned in proximity to a distal end **26**; valve **27** may be any type of valve known to those skilled in the art, for example a slit valve, a sleeve valve or a small hole valve. Pump **20** includes a reservoir, which may be refilled via an injection port **21**, and a peristaltic pump, which propel a bolus of infusate out from the reservoir through catheter **25**; an example of such a pump is the Medtronic SynchroMed™. Bolus volumes according to embodiments of the present invention may range between

approximately 0.05 mL and approximately 1 mL and delivery times may range between approximately 1 minute and approximately 60 minutes.

According to one embodiment of the present invention, as illustrated in FIG. **1**, pump **20** further includes a catheter port **22** through which a physician may insert a needle coupled to an external pressure transducer to monitor intra-catheter pressure versus time as a bolus of infusate is delivered through catheter **25**; such means to monitor pressure are well known to those skilled in the art. Alternately a pressure transducer may be built into pump **20** or catheter connector **24** to measure the intra-catheter pressure. Analysis of the intra-catheter pressure versus time during bolus delivery can be used to verify successful bolus delivery or to diagnose problems with the implantable infusion device, which prevent successful bolus delivery.

FIG. **2** is a flowchart detailing a method according to one embodiment of the present invention wherein a measured pressure versus time is analyzed. FIG. **1** illustrates a first step **200** of delivering a bolus from a pump to a catheter and a second step **210** of measuring intra-catheter pressure versus time as the bolus is being delivered. Initial analysis of the measured pressure versus time determines if pressure has increased after the first 10 seconds of bolus delivery, **220**; if pressure has not increased, the method infers that there is a large breach or disconnect in the device, **215**, but if pressure has increased a next analysis step, **230**, is performed. At step **230**, the method analyzes the pressure increase versus time to determine if it is approximately linear; if the measured pressure increase is non-linear, the method infers that there is a small leak or breach in the catheter, **225**, but if the increase is approximately linear, a next analysis step, **240**, is performed. At step **240**, the method analyzes the measured pressure versus time to determine if a pressure decrease follows the pressure increase; if the pressure continues to rise, the method infers that the catheter is occluded, **235**, while, if the pressure rises and then falls, the method infers that the bolus has been successfully delivered, **245**. Methods according to some embodiments of the present invention include controls to abort bolus delivery at any of the inference points **215**, **225** or **235**.

EXAMPLES

FIGS. **3**A–C present plots of pressure in mmHg (ordinate) versus time in seconds (abscissa) collected via an external transducer coupled to a needle inserted within catheter ports, i.e. port **22** shown in FIG. **1**, of exemplary devices. Each device included a valved infusion catheter implanted within a venous system.

FIG. **3**A is a plot of pressure versus time measured during a bolus delivery from a pump through an infusion catheter including a sleeve valve wherein there was a leak at a coupling between the catheter and the pump. FIG. **3**A illustrates a non-linear increase in pressure, from approximately 71 mmHg to approximately 177 mmHg, in between a pump start point **305** and a pump stop point **309** and corresponds to inference point **225** presented in FIG. **2**.

FIG. **3**B is a plot of pressure versus time measured during a bolus delivery from a pump through an infusion catheter, including a small hole valve, wherein the catheter was occluded by thrombus. FIG. **3**B illustrates a rise in pressure, from approximately 59 mmHg to approximately 187 mmHg, between a pump start point **315** and a pump stop point **319** and corresponds to inference point **235** presented in FIG. **2**.

FIG. **3**C is a plot of pressure versus time measured during a successful bolus injection from a pump through a catheter

including a slit valve. FIG. **3**C illustrates an approximately linear pressure increase between pump start point **325** (~73 mmHg) and a maximum pressure point **326** (~110 mmHg at ~30–35 seconds) and then a decrease in pressure from point **326** to pump stop point **329** (~107 mmHg); FIG. **3**C corresponds to inference point **245** presented in FIG. **2**.

In the foregoing detailed description, the invention has been described with reference to specific embodiments. However, it may be appreciated that various modifications and changes can be made without departing from the scope of the invention as set forth in the appended claims.

I claim:

1. A method for monitoring a bolus delivered from a pump to a fluid infusion catheter, comprising the steps of:

   delivering the bolus to the infusion catheter over a period of time lasting between approximately one minute and approximately 60 minutes; and

   observing a measured intra-catheter pressure versus time during the bolus delivery, wherein observation is made as to whether the measured pressure initially increases at an approximately linear rate followed by a decrease in measured pressure.

2. The method of claim **1**, wherein the period of time is between approximately 1 minute and 3 minutes.

3. The method of claim **1**, wherein a volume of the bolus is between approximately 0.05 mL and approximately 1 mL.

4. The method of claim **3**, wherein the volume is between approximately 0.1 mL and approximately 0.25 mL.

5. The method of claim **1**, further comprising the step of inferring a successful bolus delivery based on an observed decrease in the pressure following an observed increase in the pressure during the bolus delivery.

6. The method of claim **1**, further comprising the step of inferring a leak in the infusion catheter based on an observed non-linear increase in the pressure during the bolus delivery.

7. The method of claim **1**, further comprising the step of inferring a leak in the infusion catheter, proximal to the valve, based on an observed pressure which does not increase within approximately 10 seconds from a start of the bolus delivery.

8. The method of claim **1**, further comprising the step of inferring an occlusion of the infusion catheter based on no observed pressure decrease following an observed pressure increase, during the bolus delivery.

9. A method for controlling a bolus delivered to a pressure-responsive valve of a fluid infusion catheter, comprising the steps of:

   delivering the bolus through the infusion catheter over a period of time lasting between approximately 1 minute and approximately 60 minutes;

   monitoring intra-catheter pressure versus time during the bolus delivery; and

   aborting the bolus delivery if the pressure versus time does not conform to a predetermined pattern of pressure change over time.

10. The method of claim **9**, wherein the predetermined pattern includes an approximately linear increase in the pressure versus time.

11. The method of claim **9**, wherein the predetermined pattern includes an increase in the pressure and then a decrease in the pressure after approximately 50 seconds from a start of the bolus delivery.

12. The method of claim **9**, wherein the period of time is between approximately 1 minute and approximately 3 minutes.

13. The method of claim **9**, wherein a volume of the bolus is between approximately 0.05 mL and approximately 1 mL.

14. The method of claim **13**, wherein the volume is between approximately 0.1 mL and approximately 0.25 mL.

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